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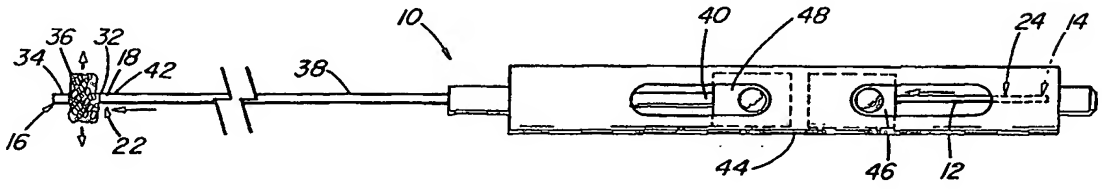

(57) Abstract

An occluder (10) insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like includes an elongated mandrel (12); a coil (18) closely positioned over part of the mandrel (12), having proximal and distal ends (20 and 22) defining a proximal segment (24) and a distal segment (26) of the mandrel (12) not covered by the coil (18); and a braid (28) positioned over and encircling all of the distal segment (26) of the mandrel (12) and preferably at least part of the wire coil (18). The distal end (16) of the elongated mandrel (12) is fixed with respect to the distal end (34) of the braid (28), while the proximal end (32) of the braid (28) is fixed with respect to the coil (18). The coil (18) and the elongated mandrel (12) are longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions, such that movement to their relatively adjacent position expands the braid (28) radially so as to occlude the body passage and form a filter (36) which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage. The coil (18) is preferably wound from flat wire, while the braid (28) is preferably formed from a woven plurality of strands (30). The occluder (10) can also include a handle (44) connected to the proximal end (14) of the mandrel (12) and to the proximal end (20) of the coil (18), for moving the mandrel (12) and coil (18) between their two relative positions.

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URETERAL STONE OCCLUDER HAVING A BRAIDED FILTER

Description

Technical Field

This invention relates generally to medical devices, and more particularly to devices useful during medical procedures for disintegrating stones, calculus or the like located in a passage in the body.

Background

Numerous medical procedures are now available for treating stones, calculus or the like which form in various passages in the body, such as kidney stones in the ureters and gallstones in the bile ducts. Such procedures involve the disintegration of the stones, calculus or the like by the application of energy to them. Kidney stones, for example, are commonly treated by ultrasonic lithotripsy, electrohydraulic lithotripsy, laser ablation or lithotripsy, shock wave lithotripsy (ESWL), or by other procedures.

While such procedures are often quite successful in disintegrating the stones, calculus or the like, they can be subject to some drawbacks when they are performed. For example, procedures for treating kidney stones typically entail infusing a relatively large volume of fluid into the renal system (renal pelvis, bladder, ureters and so on) to facilitate the passage of an endoscope or one or more catheters through the renal system. After the disintegration of kidney stones it is possible for some of the resulting fragments of the stones to migrate up the ureter towards or even into the kidney. Such migration is highly undesirable and can in some extreme cases require the performance of a percutaneous nephrostomy to drain the kidney after the disintegration procedure.

Many devices are known for anchoring catheters within various body passages or for removing undesirable materials from them. However, these devices generally are not adapted for preventing the migration of fragments from stones, calculus or the like within body passages, and generally would not be viewed as acceptable for preventing such migration. For example, many known ureteral or other catheter anchors (for example, the balloons of the well-known Foley catheters)

are not porous. While it might at first be thought that they could prevent the migration of fragments up the ureter or other body passage, it should become clear upon reflection that such nonporous anchors would not permit any dispersion of the energy applied to break up the stones, calculus or the like. Indeed, the fragments might well possess sufficient energy from the disintegration procedure to force themselves between the nonporous anchor and the ureteral wall or other body passage. The ureteral wall or other wall itself might even be damaged by such forcing, or by unduly severe expansion or inflation of the anchor in order to prevent such forcing.

Catheters or anchors used for other purposes do not solve these problems. For example, U.S. Patent No. 3,996,938 (Clark, III, Dec. 14, 1976) discloses a flexible catheter for removing blood clots (thrombi) from the vascular system. The catheter includes a mesh sleeve positioned between the round ended tip of a flexible plunger wire and the end of an elongate flexible portion of a guide tube, in which the plunger wire slidably extends through the guide tube. The mesh is normally tubular or cylindrical in shape, but is expanded by drawing the plunger wire back. The catheter is withdrawn while the mesh is still expanded, carrying the clot or clots with it. The elongate flexible portion of the guide tube is preferably formed of tightly wound spring wire.

While the device of the Clark, III, patent may function adequately, it may be subject to several drawbacks during its use. For example, the device provides no protection for the mesh sleeve or for the elongated flexible portion (the wound spring wire) before, during or after its introduction into the body. Moreover, it is now well known that wound wire coils or springs of relatively small diameters, e.g., less than or equal to about 3 French, are undesirably subject to deformation due to elongation and/or compression during use. Further, the patent contains no suggestion that the disclosed device is useful in the treatment of stones, calculus or the like or is useful to prevent the migration of fragments of them, or to allow fragments of them to exit the body by the normal path of evacuation from the passage in which the stones, calculus or the like are located.

Other devices do not fully solve these problems, or have drawbacks of their own. For example, U.S. Patent No. 5,041,093 (Chu, Aug. 20, 1991) discloses a drainage catheter which includes an elongated flexible tubular member having a woven or braided foraminous tube near its distal end as an anchor. The foraminous tube is translatable from an extended or cylindrical configuration (in which it is easy to place the catheter in the organ to be drained) to an ovoid or other anchoring configuration. Like the Clark, III, patent, the Chu patent does not disclose any means for protecting the woven tube before or during introduction. Moreover, the Chu patent appears to contain no suggestion as to how the device disclosed in it could be or should be modified to possess a structure or pore size suitable for blocking fragments of kidney stones, gall stones or the like, or that it could be or should be modified so that the foraminous tube is dimensioned to closely match the diameter of the vessel or other body passage in which the anchor is disposed. Indeed, this last modification would be contrary to the teachings of the Chu patent, since such a modification would defeat the purpose of the Chu patent, that is, to provide an anchor by giving the foraminous tube a diameter significantly larger than the diameter of the vessel or passage in which it is located.

Other devices are known which meet some but not all of these concerns. For example, U.S. Patent No. 4,921,484 (Hillstead, May 1, 1990) discloses a mesh balloon catheter device which includes a catheter, a tubular mesh of woven interlaced filaments connected to the distal end of the catheter, and a mechanism for moving the distal end of the tubular mesh towards the proximal end of the tubular mesh so that the mesh balloons laterally outward. The mechanism for moving the distal end of the tubular mesh includes a handle, and the mesh is disclosed as being useful for holding the catheter in place in the bladder or bile tract, or for filtration in either a drainage application or as an addition to a coronary angioplasty balloon catheter procedure. The device disclosed in the Hillstead patent appears to be subject to many of the limitations and drawbacks noted above.

Similarly, U.S. Patent No. 4,790,812 (Hawkins, Jr., et al., Dec. 13, 1988) discloses an apparatus for removing a target object from a body passageway. The apparatus includes a cutting tip and a downstream parachute basket made of spiral

wire for catching fragments produced by the cutting tip. The apparatus is disclosed as being useful for fragmenting relatively hard objects such as atheroma or kidney stones. The basket may be stowed within a sheath catheter and can include a porous fabric web between the spiral wires of the parachute. The specification of the patent, at column 6, lines 45-63, notes that the apparatus may be used, without the parachute basket, in conjunction with conventional shock wave lithotripsy (ESWL) techniques for the removal of kidney stones.

It should be clear that it would be highly desirable to have a device which is straightforward in construction and is simple to use, and which affirmatively prevents the undesired migration of fragments of stones, calculus or the like in a body passage towards the kidney or other organ from which the passage leads, yet which permits the dispersion of the energy applied during the disintegration procedure. It would also be highly desirable to have a device which was of relatively small diameter, for example, equal to or less than about 3 French, which did not possess the elongation and compression problems associated with wound wire coils of such a diameter.

Summary

The foregoing problems are solved and a technical advance is achieved in an illustrative occluder for the ureter or another body passage. Applicant has discovered that the migration of fragments of stones, calculus or the like resulting from ultrasonic lithotripsy, electrohydraulic lithotripsy, laser ablation or lithotripsy, or the like, can reliably be limited by the insertion of a particular occluder into a body passage such as an ureter before disintegration of the stones, calculus or the like. The occluder comprises an elongated mandrel and a flexible tubular shaped arrangement mounted around the mandrel for relative longitudinal movement along the mandrel. The arrangement comprises a first flexible tubular shaped part mounted for relative reciprocal movement along the mandrel and a second flexible part with a proximal region connected to the first part and with a distal region connected to a distal part of the mandrel. The second and first parts are constructed in such a manner that the second part radially expands when longitudinally compressed by longitudinal movement of the first part in a distal direction. The second part when

radially expanded forms a filter to occlude the body passage whilst simultaneously permitting flow of fluid in the body passage. Particularly, the second part is in the form of a braid formed from one or more strands or wires extending between the distal end of the first part and the distal end of the mandrel. More particularly, the braid extends over at least a part of the first part with the proximal end of the braid connected to the external surface of the first part. Even more particularly, an introducer sheath is able to surround the first and second parts when the second part is in a non-radially expanded phase.

In another aspect, the first part is in the form of a flexible coil capable of longitudinally compressing and radially expanding the second part.

The first part can either be in the form of a flexible tube with or without a helical channel cut in the outer surface, or it can be in the form of a coil.

The second part can be in the form of a woven braid or in the form of a coil which has a flexibility and pitch enabling it to radially expand when longitudinally compressed. The proximal end of the second part can be connected to the distal end of the first part, or they can be in an overlapping relationship.

It is not essential for the first part to be a coil, and it is not essential for the second part to be a multi-stranded braid. The second part must possess two properties. Firstly, it must be sufficiently flexible so that the occluder works in a satisfactory manner and secondly, it must be able to impart positive distal movement to the second part, when the first part is pushed in a distal direction relative to the mandrel. Both of these properties can be achieved by a thin plastic tube with a longitudinally extending helix cut in the outer surface. The second part need not be formed from a plurality of woven strands. One strand can be sufficient. The term "braid" implies a weaving action of which a fine wire coil should function satisfactorly providing the pitch was suitable.

The braid does not need to be "position over" the "coil". It can be nearly connected the distal end of the coil, and that connection is only needed for the purposes of withdrawal. The radial expansion can be achieved by a mere pushing action. A "proximal segment" is not required on the mandrel; however, lack thereof, would make the operation of the handle somewhat complicated.

In another aspect, the occluder includes a collapsed but expandable filter which is positioned above the stone, calculus or the like, and which is then expanded before the disintegration procedure is performed. Such positioning is preferably carried out under ureteroscopic (direct vision) control.

More particularly, Applicant has discovered an occluder insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like, which first comprises an elongated mandrel and a coil closely positioned over part of the mandrel. The coil has proximal and distal ends defining proximal and distal segments of the mandrel which are not covered by the coil. The occluder also comprises a braid positioned over and encircling all of the distal segment of the mandrel and preferably, although not necessarily, positioned over and encircling at least part of the wire coil. The coil is preferably wound from flat wire, while the braid is preferably formed from a woven plurality of strands.

The distal end of the elongated mandrel is fixed with respect to the distal end of the braid, while the proximal end of the braid is fixed with respect to the coil. The coil and the elongated mandrel are longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions; movement to their relatively adjacent position expands the braid radially so as to occlude the body passage and form a filter which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage. This simultaneously permits some of the energy employed during disintegration of the stones, calculus or the like to be dispersed both upstream and downstream in the passage.

Preferably, the occluder additionally comprises a handle connected to the proximal end of the mandrel and to the proximal end of the coil, for moving the mandrel and coil between their two relative positions. Also preferably, the occluder further comprises a protective outer sheath slidable over the braid when the wound coil and the elongated mandrel are in their relatively spaced-apart position.

In a first aspect, then, the occluder is insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising: an elongated mandrel having a proximal end and a distal end; a coil closely positioned over part of the elongated

mandrel, the coil having a proximal end and a distal end, the proximal and distal ends of the coil defining a proximal segment and a distal segment of the elongated mandrel not covered by the coil; and a braid positioned over and encircling all of the distal segment of the elongated mandrel and at least part of the wire coil, the braid having a proximal end and a distal end; wherein the coil and the elongated mandrel are longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions; wherein the distal end of the elongated mandrel is fixed with respect to the distal end of the braid; wherein the proximal end of the braid is fixed with respect to the coil; and wherein movement of the coil and the elongated mandrel to their relatively adjacent position expands the braid radially so as to occlude the body passage and form a filter which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage.

This first aspect of the occluder also comprises various additional features as disclosed.

In a second aspect, the occluder is insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising: an elongated mandrel having a proximal end and a distal end; a coil wound from flat wire and closely positioned over part of the elongated mandrel, the coil having a proximal end and a distal end, the proximal and distal ends of the coil defining a proximal segment and a distal segment of the elongated mandrel not covered by the coil; the coil and the elongated mandrel being longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions; a braid formed from a woven plurality of strands and positioned over and encircling all of the distal segment of the elongated mandrel, the braid having a proximal end and a distal end; and an outer sheath slidable over the braid when the coil and the elongated mandrel are in their relatively spaced-apart position; wherein the distal end of the elongated mandrel is fixed with respect to the distal end of the braid; wherein the proximal end of the braid is fixed with respect to the coil; and wherein movement of the coil and the elongated mandrel to their relatively adjacent position expands the braid radially so as to occlude the body passage and form a filter which blocks the migration of fragments

in the body passage while allowing the flow of fluid in the body passage. This second aspect of the occluder differs from the first aspect in that the coil is wound from flat wire, in that the braid is formed from a woven plurality of strands, in that the proximal end of the braid is affixed to the distal end of the coil, and in that it further includes an outer sheath slidable over the braid when the coil and mandrel are in their relatively spaced-apart position.

In a final aspect, to an occluder is insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising: an elongated mandrel having a proximal end and a distal end; a coil wound from flat wire and closely positioned over part of the elongated mandrel, the coil having a proximal end and a distal end, the proximal and distal ends of the coil defining a proximal segment and a distal segment of the elongated mandrel not covered by the coil; the coil and the elongated mandrel being longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions; a braid formed from a woven plurality of strands and positioned over and encircling all of the distal segment of the elongated mandrel and the substantial length of the wire coil, the braid having a proximal end and a distal end; a handle connected to the proximal end of the elongated mandrel and the proximal end of the coil; and an outer sheath slidable over the braid when the coil and the elongated mandrel are in their relatively spaced-apart position, and wherein the handle includes a sheath slider to which the outer sheath is connected; wherein the distal end of the elongated mandrel is fixed with respect to the distal end of the braid; wherein the proximal end of the braid is fixed with respect to the coil; wherein movement of the coil and the elongated mandrel to their relatively adjacent position expands the braid radially so as to occlude the body passage and form a filter which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage; wherein the proximal end of the braid is affixed to the proximal end of the coil; wherein the braid is cylindrically shaped when the coil and the elongated mandrel are in their relatively spaced-apart position; and wherein the proximal end of the elongated mandrel is fixed to the handle, and wherein the handle includes a coil slider to which the proximal end of the coil is connected. This

third aspect of the occluder is directed to a particular species of the first aspect of the occluder, in which the braid covers the substantial length of the coil.

The ureteral or other occluder is particularly advantageous in that the migration of large fragments of stone, calculus or the like further up the ureter or other body passage is affirmatively avoided, since the filter not only traps such fragments, but allows at least some of the energy applied during the disintegration procedure to be dispersed both up and down the ureter or other body passage. It must be remembered, however, that while the occluder finds its greatest utility as a ureteral occluder, and while its preferred embodiment is disclosed as a ureteral occluder, the occluder can also be used in a variety of other body passages, including (but not limited to) the bile ducts.

Brief Description of the Drawings

FIG. 1 is a side view of the preferred embodiment of the occluder;

FIG. 2 is a partial cross-sectional view of the preferred embodiment of the occluder;

FIG. 3 is a cross-sectional view of the occluder of FIG. 1 taken along line 3 - 3;

FIG. 4 is a side view of the preferred embodiment of the occluder during use;

FIG. 5 is another side view of the preferred embodiment of the occluder during use; and

FIG. 6 is a partial cross-sectional view of another preferred embodiment of the occluder.

Detailed Description

With reference now to FIG. 1, an occluder 10 is thereshown, which is insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage. The occluder 10 first comprises an elongated mandrel 12 having a proximal end 14 and a distal end 16. The mandrel 12 is composed of a medical grade material such as stainless steel or another alloy, nitinol, or a synthetic material. When the occluder 10 is intended for use in the ureter, the mandrel 12 is conveniently composed of a 0.229 mm (0.009

in.) wire, and is about 86 cm long. The particular dimensions of the mandrel 12 should of course be selected in view of the body passage in which the occluder 10 is to be placed.

Still with reference to FIG. 1, but with further reference to FIGs. 2 and 3, the occluder 10 next comprises a coil 18 closely positioned over part of the mandrel 12. The coil 18 is composed of a medical grade material such as stainless steel or another alloy, nitinol, or a synthetic material. The coil 18 is preferably wound from a flat metal wire and conveniently has an overall diameter of 0.457 mm (0.018 in.). Also preferably, when the occluder 10 is employed in the ureter, the coil 18 has an overall length of about 75 cm.

The coil 18 has a proximal end 20 and a distal end 22, which respectively define a proximal segment 24 and a distal segment 26 of the elongated mandrel not covered by the coil 18. When the occluder 10 is employed in the ureter, the proximal uncovered segment 24 of the mandrel 12 is about 8 cm in length, while the distal uncovered segment 26 of the mandrel 12 is about 3 cm in length.

The occluder 10 further comprises a braid 28 positioned over and encircling all of the distal segment 26 of the elongated mandrel 12. The braid can be woven or formed from one or more strands of wire. The braid 28 is also positioned over and encircles at least part of, and preferably covers the substantial length of, the coil 18. The braid 28 has a proximal end 32 and a distal end 34, the proximal end 32 of the braid 28 being fixed with respect to the coil 18, and the distal end 16 of the mandrel 12 being fixed with respect to the distal end 34 of the braid 28. The braid 28 is preferably formed from a woven plurality of strands 30. The strands 30 are composed of a suitable medical grade material, such as nitinol, stainless steel, another metal alloy or a polymer.

Conveniently, about a 3 mm segment of soft solder connects the distal end 34 of the braid 28 to the distal end 16 of the mandrel 12, while about a 2 to 3 mm segment of hard solder affixes the proximal end 32 of the braid to the coil 18, preferably to the proximal end 20 of the coil 18. Preferably, about a 2 to 3 mm segment of soft solder also secures the braid 28 to the distal end 22 of the coil 18, between the proximal and distal ends 32 and 34 of the braid 28. This essentially

makes the tip of the occluder 10, formed by the distal end 34 of the braid 28 and the distal end 16 of the mandrel 12, atraumatic. However, to ensure that the tip of the occluder 10 is atraumatic, a further round bead of solder can be placed on the braid distal end 34 and the mandrel distal end 16. Alternatively, a small metal ball can be soldered or otherwise attached to them.

Although the coil 18 and the elongated mandrel 12 are thus both secured to the braid 28, the coil 18 and mandrel 12 must still be longitudinally moveable with respect to one another. It is therefore important that the two segments of solder affixing the braid 28 to the coil 18 be applied in a manner which does not interfere with such relative movement.

More particularly, the coil 18 and the elongated mandrel 12 are moveable between two positions, one in which their distal ends 22 and 16 are relatively adjacent (designated herein as "the relatively adjacent position"), and another in which their distal ends 22 and 16 are relatively more distant from one another (designated herein as "the relatively spaced-apart position"). It is this latter spaced-apart position that is shown in FIGs. 1 and 2. When the coil 18 and the mandrel 12 are in their relatively spaced-apart position, the braid 28 is generally cylindrically shaped.

As shown in FIG. 5, movement of the coil 18 and mandrel 12 to their relatively adjacent position causes the proximal end 32 and the distal end 34 of the braid 28 to approach one another, expanding the braid 28 radially. The braid 28 expands radially so as to occlude the body passage in which the occluder 10 is placed, for example, in the ureter, and thereby form a filter 36 which blocks the migration of any fragments of stone, calculus or the like, while allowing the flow of fluid in the body passage. This permits the upstream dispersion of at least part of the disintegrating energy applied to the stone, calculus or the like, without fear that the fragments with migrate upstream.

The occluder 10 preferably further comprises a mechanism for causing relative movement of the coil 18 and the mandrel 12. Such a mechanism is exemplified by a handle 44 connected to the proximal end 14 of the mandrel 12 and the proximal end 20 of the coil 18. One of the coil 18 and the mandrel 12 is fixed to the

handle 44, while the other is slidably connected to the handle 44. Conveniently, and to provide good resistance to transverse deflection and kinking or deformation during use, the proximal end 14 of the elongated mandrel 12 is affixed to the handle 44, while the proximal end 20 of the coil 18 is slidably connected to the handle 44 by a coil slider 46 contained in the handle 44. The coil slider 46 slides over the uncovered proximal segment 24 of the mandrel 12. Of course, a variety of conventional elements (not shown) can be used to connect the mandrel 12 to the handle 44, and the coil 18 to the handle 44, in particular, to the coil slider 46.

For protecting the braid 28 before and during its introduction into the desired body passage, and to facilitate introduction of the occluder 10 into the body passage, the occluder 10 preferably further comprises an outer sheath 38 slidable over the braid 28 when the coil 18 and the elongated mandrel 12 are in their relatively spaced-apart position. The sheath 38 is conveniently operated by and connected to the handle 44 by a sheath slider 48 contained in the handle 44. The sheath slider 48 fits over the coil 18 and mandrel 12, distal to the proximal end 20 of the coil 18. Withdrawal of the sheath 38 so as to expose the braid 28 is shown in FIG. 4. A variety of conventional connecting elements (not shown) can be used to connect the outer sheath 38 to the handle 44, and in particular, to the sheath slider 48.

As noted above, it is preferred but not absolutely necessary that the braid 28 encircle and cover the substantial length of the coil 18, up to the coil slider 46 in the handle 44. The reason for such preference is a practical one. It has been found in a variety of devices that wound wire coils of relatively small overall diameter, equal to or less than about 3 French, are subject to elongation and compressive deformation when introduced into body passages. The preferred occluder overcomes the drawbacks of such deformation by allowing the braid 28 to extend the substantial length of the coil 18, thereby supporting it and avoiding the undesired deformation. However, in diameters greater than about 3 French, wound wire coils are generally able to sustain themselves during introduction into body passages, so the support provided by the braid 28 in smaller occluders isn't necessary in larger occluders. Accordingly, as shown in FIG. 6, in occluders having a diameter greater

than about 3 French, the braid 28 need not cover the entire coil 18, but need only be connected to the distal end 16 of the mandrel 12 and the distal end 20 of the coil 18. More particularly, the proximal end 32 of the braid 28 can be fixed to the distal end 22 of the coil 18 by about a 2 to 3 mm segment of either hard or soft solder. Such occluders are otherwise constructed in the same manner as the occluder 10 shown in FIGs. 1 through 5, and include the outer sheath 38 slidable over the braid 28 when the coil 18 and mandrel 12 are in their relatively spaced-apart position.

Use of the occluder 10 to prevent the migration of fragments of stone, calculus or the like during disintegration procedures can now be readily understood. The occluder 10 is first arranged as shown in FIG. 1, with the coil slider 46 moved proximally so that the braid 28 is in a generally cylindrical shape, and with the sheath slider 48 moved distally so that the sheath 38 covers the braid 28. The patient is then prepared for the introduction of the occluder 10 into the desired body passage and for performance of the disintegration procedure. For example, it may be desirable before lithotripsy of kidney stones to infuse the renal system of the patient with a suitable fluid. Once the patient is prepared, the occluder 10 is introduced into the ureter until the braid 28 lies upstream of the stone, calculus or the like to be disintegrated. Such introduction is most conveniently carried out via ureteroscopic (direct vision) control, although other monitoring methods may be suitable for other body passages.

Once the occluder 10 is in position, the sheath slider 48 on the handle 44 is moved proximally so as to withdraw the sheath 38 from the braid 28 (Fig. 4). The coil slider 46 is then moved distally (Fig. 5) to radially expand the braid 28 so as to occlude the ureter or other body passage and form the filter 36 which blocks the migration of fragments while allowing the flow of fluid and the dispersion of at least part of the energy to be applied for disintegrating the stone, calculus or the like.

The desired lithotripsy or ablative procedure is then performed, with assurance that undesired migration of fragments is prevented. Once the procedure is complete, the coil slider 46 is moved proximally to collapse the filter 36, and the sheath slider 48 is moved distally to slide the outer sheath 38 over the braid 28. The occluder 10 is then removed from the ureter or other body passage.

It should be clear that the occluder for the ureter or another body passage is particularly advantageous in that the undesired migration of fragments of stone, calculus or the like is affirmatively prevented, while at least some of the energy applied during the disintegration procedure is dispersed both up and down the ureter or other body passage.

Any undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present occluder are not believed to be critical to the achievement of the indicated advantages, so long as the elements possess the characteristics needed for them to perform as disclosed. The selection of these and other details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure.

Industrial Applicability

This occluder is useful in performing surgical procedures, and therefore finds applicability in human and veterinary medicine.

It is to be understood, however, that the above-described occluder is merely an illustrative embodiment of the principles of this invention, and that other occluders and methods for using them may be devised by those skilled in the art, without departing from the spirit and scope of the invention. It is also to be understood that the occluder is directed to embodiments both comprising and consisting of the disclosed parts.

Claims

1. An occluder (10) insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus, or the like in or associated with the passage, said occluder comprising an elongated mandrel (12), a flexible tubular shaped arrangement (18, 28) mounted around the mandrel for relative longitudinal movement along the mandrel, wherein the said arrangement comprises a first flexible tubular shaped part (18) mounted for relative reciprocal movement along the mandrel; and a second flexible part (28) with a proximal region connected to the said first part, and with a distal region connected to a distal part of the mandrel; and wherein the said first and second parts are constructed in such a manner that the second part radially expands when longitudinally compressed by longitudinal movement of the first part in a distal direction, the second part when radially expanded forming a filter to occlude the body passage whilst simultaneously permitting flow of fluid in the body passage.

2. An occluder according to claim 1, wherein the said second part is in the form of a braid formed from one or more strands or wires extending between the distal end of the said first part and the distal end of the mandrel.

3. An occluder according to claim 2, wherein the braid extends over at least a part of the said first part, with the proximal end of the braid connected to the external surface of the said first part.

4. An occluder according to claim 3, wherein an introducer sheath is able to surround the said first and second parts when the second part is in a non-radially expanded phase.

5. An occluder according to any one preceding claim, wherein the said first part is in the form of a flexible coil capable of longitudinally compressing and radially expanding the said second part.

6. An occluder (10) insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising:

an elongated mandrel (12) having a proximal end (14) and a distal end (16);

a coil (18) closely positioned over part of the elongated mandrel (12), the coil (18) having a proximal end (20) and a distal end (22), the proximal and distal ends (20 and 22) of the coil (18) defining a proximal segment (24) and a distal segment (26) of the elongated mandrel (12) not covered by the coil (18); and

a braid (28) positioned over and encircling all of the distal segment (26) of the elongated mandrel (12) and at least part of the wire coil (18), the braid (28) having a proximal end (32) and a distal end (34);

wherein the coil (18) and the elongated mandrel (12) are longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions;

wherein the distal end (16) of the elongated mandrel (12) is fixed with respect to the distal end (34) of the braid (28);

wherein the proximal end (32) of the braid (28) is fixed with respect to the coil (18); and

wherein movement of the coil (18) and the elongated mandrel (12) to their relatively adjacent position expands the braid (28) radially so as to occlude the body passage and form a filter (36) which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage.

7. The occluder (10) according to claim 6, wherein the proximal end (32) of the braid (28) is affixed to the proximal end (20) of the coil (18).

8. The occluder (10) according to claim 6, wherein the braid (28) covers the substantial length of the coil (18).

9. The occluder (10) according to claim 6, wherein the braid (28) is cylindrically shaped when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position.

10. The occluder (10) according to claim 6, further comprising an outer sheath (38) slidable over the braid (28) when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position.

11. The occluder (10) according to claim 6, wherein the coil (18) is wound from flat wire.

12. The occluder (10) according to claim 6, further comprising a handle (44) connected to the proximal end (14) of the elongated mandrel (12) and the proximal end (20) of the coil (18).

13. The occluder (10) according to claim 12, wherein the proximal end (14) of the elongated mandrel is fixed to the handle (44), and wherein the handle (44) includes a coil slider (46) to which the proximal end (20) of the coil (18) is connected.

14. The occluder (10) according to claim 12, further comprising an outer sheath (38) slidable over the braid (28) when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position, and wherein the handle (44) includes a sheath slider (48) to which the outer sheath (34) is connected.

15. The occluder (10) according to claim 6, wherein the braid (28) is formed from a woven plurality of strands (30).

16. The occluder (10) according to claim 15, wherein the strands (30) of the braid (28) are composed of nitinol, stainless steel, a metal alloy or a polymer.

17. An occluder (10) insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising:

an elongated mandrel (12) having a proximal end (14) and a distal end (16);

a coil (18) wound from flat wire and closely positioned over part of the elongated mandrel (12), the coil (18) having a proximal end (20) and a distal end (22), the proximal and distal ends (20 and 22) of the coil (18) defining a proximal segment (24) and a distal segment (26) of the elongated mandrel (12) not covered by the coil (18); the coil (18) and the elongated mandrel (12) being longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions;

a braid (28) positioned over and encircling all of the distal segment (26) of the elongated mandrel (12), the braid (28) having a proximal end (32) and a distal end (34); and

an outer sheath (38) slidable over the braid (28) when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position;

wherein the distal end (16) of the elongated mandrel (12) is fixed with respect to the distal end (34) of the braid (28);

wherein the proximal end (32) of the braid (28) is fixed with respect to the coil (18); and

wherein movement of the coil (18) and the elongated mandrel (12) to their relatively adjacent position expands the braid (28) radially so as to occlude the body passage and form a filter (36) which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage.

18. The occluder (10) according to claim 17, wherein the proximal end (32) of the braid (28) is fixed to the distal end (22) of the coil (18).

19. The occluder (10) according to claim 17, wherein the braid (28) is cylindrically shaped when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position.

20. The occluder (10) according to claim 17, further comprising a handle (44) connected to the proximal end (14) of the elongated mandrel (12) and the proximal end (20) of the coil (18).

21. The occluder (10) according to claim 20, wherein the proximal end (14) of the elongated mandrel is fixed to the handle (44), and wherein the handle (44) includes a coil slider (46) to which the proximal end (20) of the coil (18) is connected.

22. The occluder (10) according to claim 20, wherein the handle (44) includes a sheath slider (48) to which the outer sheath (34) is connected.

23. The occluder (10) according to claim 17, wherein the braid (28) is formed from a woven plurality of strands (30).

24. The occluder (10) according to claim 23, wherein the strands (30) of the braid (28) are composed of nitinol, stainless steel, a metal alloy or a polymer.

25. An occluder (10) insertable into a body passage for limiting the migration of fragments resulting from the disintegration of stones, calculus or the like in the passage, comprising:

an elongated mandrel (12) having a proximal end (14) and a distal end (16);

a coil (18) wound from flat wire and closely positioned over part of the elongated mandrel (12), the coil (18) having a proximal end (20) and a distal end (22), the proximal and distal ends (20 and 22) of the coil (18) defining a proximal segment (24) and a distal segment (26) of the elongated mandrel (12) not covered by the coil (18); the coil (18) and the elongated mandrel (12) being longitudinally moveable with respect to one another between relatively adjacent and relatively spaced-apart positions;

a braid (28) formed from a woven plurality of strands (30) and positioned over and encircling all of the distal segment (26) of the elongated mandrel (12) and the substantial length of the wire coil (18), the braid (28) having a proximal end (32) and a distal end (34);

a handle (44) connected to the proximal end (14) of the elongated mandrel (12) and the proximal end (20) of the coil (18); and

an outer sheath (38) slidable over the braid (28) when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position, and wherein the handle (44) includes a sheath slider (48) to which the outer sheath (34) is connected;

wherein the distal end (16) of the elongated mandrel (12) is fixed with respect to the distal end (34) of the braid (28);

wherein the proximal end (32) of the braid (28) is fixed with respect to the coil (18);

wherein movement of the coil (18) and the elongated mandrel (12) to their relatively adjacent position expands the braid (28) radially so as to occlude the body passage and form a filter (36) which blocks the migration of fragments in the body passage while allowing the flow of fluid in the body passage;

wherein the proximal end (32) of the braid (28) is affixed to the proximal end (20) of the coil (18);

wherein the braid (28) is cylindrically shaped when the coil (18) and the elongated mandrel (12) are in their relatively spaced-apart position; and

wherein the proximal end (14) of the elongated mandrel is fixed to the handle (44), and wherein the handle (44) includes a coil slider (46) to which the proximal end (20) of the coil (18) is connected.

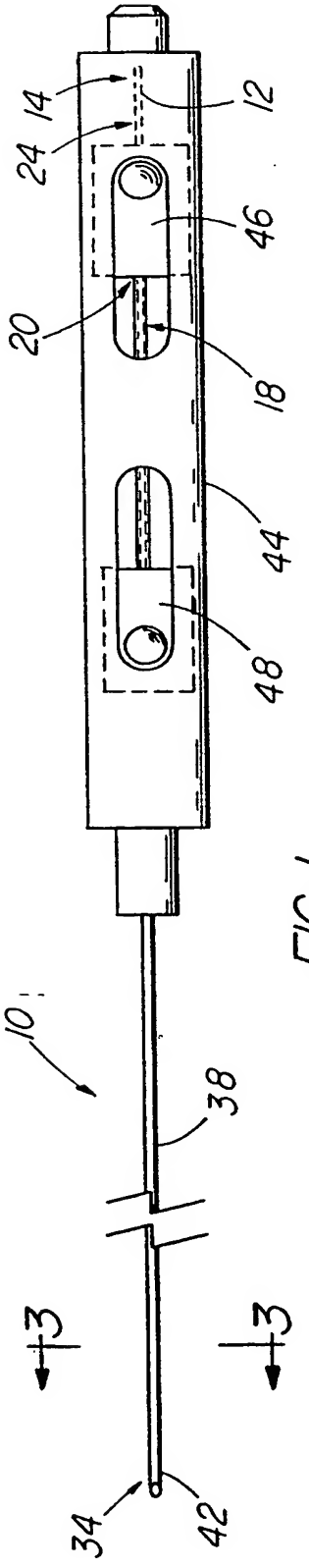

FIG. 1

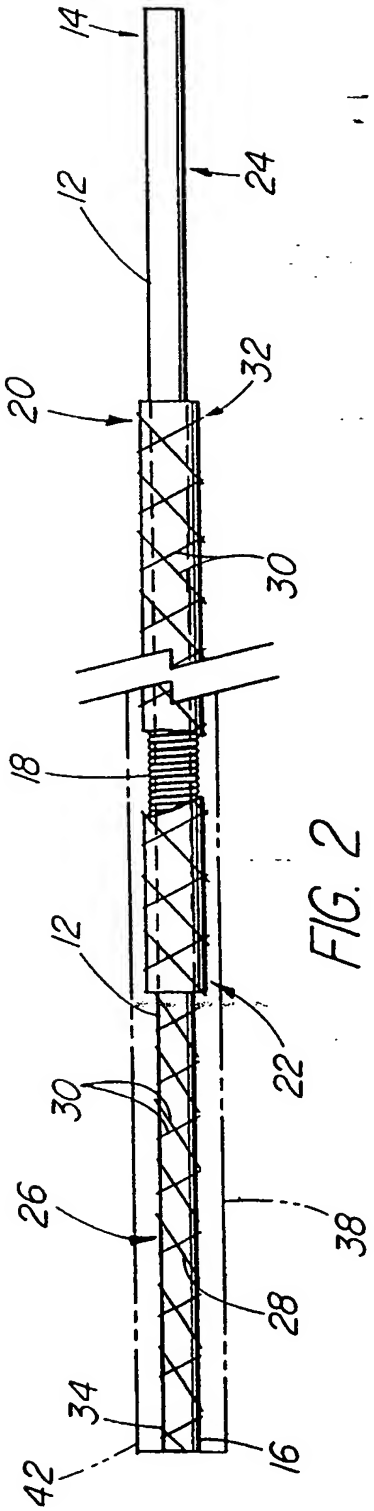

FIG. 2

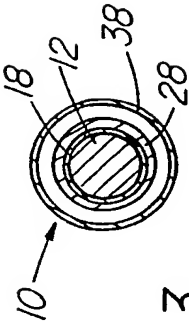

FIG. 3

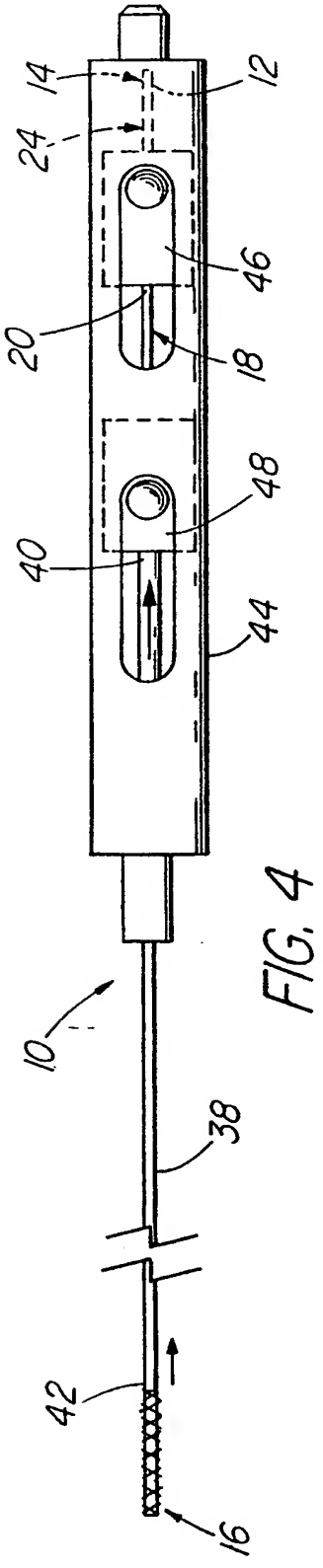

FIG. 4

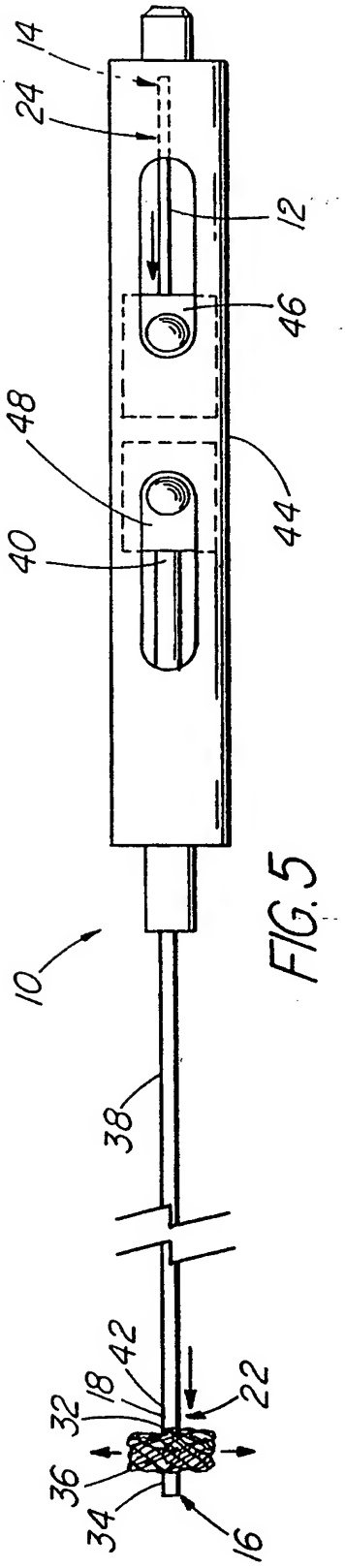

FIG. 5

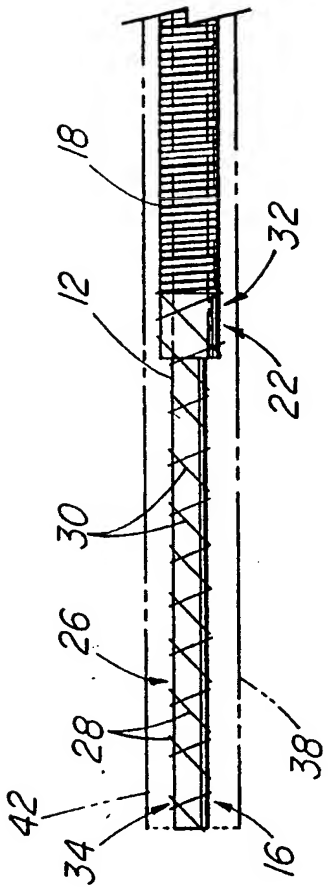

FIG. 6

INTERNATIONAL SEARCH REPORT

Intern .a .plication No
PCT/US 97/23881

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 1 677 671 A (COUNCILL) 17 July 1928 see the whole document	1-3,5-7, 9,11-13, 15,16
Y		10,14, 17-25
X	WO 93 02732 A (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 18 February 1993 see page 5, line 19 - page 6, line 36 see page 7, line 24-30 see page 11, line 18-23; figures	1-5
Y		10,14, 17-25
X	GB 2 020 557 A (WILLY RÜSCH GMBH & CO. KG) 21 November 1979 see abstract; claims; figures	1-5

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
9 April 1998	20/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

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INTERNATIONAL SEARCH REPORT

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PCT/US 97/23881

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DE 39 13 935 A (WIEDECK) 31 October 1990 see the whole document	1-5
A	US 3 996 938 A (CLARK, III) 14 December 1976 cited in the application see the whole document	1-5
A	US 5 059 199 A (OKADA ET AL.) 22 October 1991 see column 5, line 31; figure 2	11,17,25
P,X	WO 97 41782 A (BOSTON SCIENTIFIC CORPORATION) 13 November 1997 see the whole document	1-7,9-25

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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